NASMD

National Association of State Medicaid Directors

an affiliate of the American Public Human Services Association

March 15, 2010

Ms. Charlene Frizzera
Acting Administrator
Centers for Medicare & Medicaid Services
7500 Security Blvd.
Baltimore, MD 21244

Re: Proposed Rule*: Medicare and Medicaid Programs; Electronic Health Record Incentive Program;* 75 F.R.; CMS-0033-P

Dear Ms. Frizzera:

The National Association of State Medicaid Directors (NASMD) respectfully submits this comment letter on the Medicare and Medicaid Programs; Electronic Health Record Incentive Program proposed rules, published in the January 13, 2010 Federal Register. This notice of proposed rulemaking (NPRM) is designed to implement the provisions of the American Recovery and Reinvestment Act of 2009 (ARRA) that provide incentive payments to eligible professionals (EPs) and eligible hospitals participating in Medicare and Medicaid programs that adopt and meaningfully use certified electronic health record (EHR) technology.

These comments were developed through a workgroup of more than 25 state Medicaid officials led by NASMD with support from the Center for Health Care Strategies (CHCS) and represent the opinion of NASMD and its members. NASMD is a bipartisan, professional, nonprofit organization of representatives of state Medicaid agencies (including the District of Columbia and the territories). Since 1979, NASMD has been affiliated with the American Public Human Services Association (APHSA). The primary purposes of NASMD are: to serve as a focal point of communication between the states and the federal government, and to provide an information network among the states on issues pertinent to the Medicaid program. The Center for Health Care Strategies, Inc. is a non-profit health care resource center with the mission to improve the quality of health care in Medicaid.

We understand that this proposed rule would specify the initial criteria that eligible providers and hospitals must meet to qualify for the incentive payment, calculation of the payment amounts and other program participation requirements. NASMD appreciates

CMS' work to develop these regulations, and is pleased to provide you with the following comments.

GENERAL COMMENTS

As CMS has noted, states are fertile laboratories for testing and evaluating strategies for Health Information Technology (HIT) adoption, provider incentives, privacy and security and beneficiary/stakeholder involvement. States that received Medicaid Transformation Grants, authorized by the Deficit Reduction Act of 2005, made major strides towards transforming delivery systems through HIT. These grants provided the foundation for HIT initiatives in many states and the lessons learned have broad applicability for the current HIT/E implementation activities in the United States. These states developed expertise and successfully implemented a wide range of health information projects and initiatives that will support the President's goal for adoption and meaningful use of electronic health records and health information exchange.

The Medicaid Transformation Grants provided many important lessons that can help guide the implementation of the provider incentive program. Some of the most relevant lessons learned include:

- Timelines must be appropriate to facilitate adequate adoption outcomes. Based on the Transformation Grants, we believe three years is the minimum amount of time needed for a broad HIT implementation project;
- Public/private partnerships can be effective ways to facilitate HIT adoption. Issues around governance, coordination, and broad stakeholder engagement are challenging and will require significant resources and time;
- Concerns about privacy, security, and consent must be addressed and negotiated at the beginning of the project. HIT and HIE adoption require the storage and transmission of large amounts of sensitive health information, and HIPAA considerations must be addressed before the projects commence;
- Procurement processes are slow and can cause significant delays;
- Once providers adopt, there are other change management initiatives that must be addressed. Providers and their staff need constant training and reinforcement about the new processes and procedures necessary to utilize the technology;
- The HIT/HIE models should have multiple benefits to the providers, with a software model that includes information from multiple payers, administrative functions, active interaction with the electronic health record, and health information that enables providers to view test results; and
- Incentives are important tools to spur adoption, but provider adoption and utilization is slow and unpredictable. There are always mitigating circumstances that have unintended effects on providers' adoption efforts.

The HITECH provisions under ARRA established that the States will be responsible for much of the planning, implementation, oversight of electronic health records (EHR) adoption, and the statewide expansion of health information exchanges (HIE). CMS

understands that in many cases, the Medicaid Program is driving statewide HIT provider adoption. State Medicaid agencies are charged with HIT planning, assessing provider EHR readiness and planning adoption support, and developing the necessary Medicaid HIT infrastructure to support Medicaid participation in HIEs.

Medicaid programs have a strong sense of responsibility and accountability for achieving the goal of meaningful use of EHRs in Medicaid. This endeavor will require dedicated and skilled Medicaid agency staff in order to achieve success. State Medicaid programs need continued support and flexibility if they are going to be able to implement EHR incentive programs and assure meaningful use of EHRs by providers as early as January 2011. It is critical that CMS provide states with an adequate amount of resources, time, and technical assistance to plan and administer this major program.

GUIDING PRINCIPLES

The NASMD workgroup adopted the following guiding principles that directed states' comments related to the Medicaid EHR incentive program and this proposed rule. The following principles are based on the lessons learned from several years of experience with the Medicaid Transformation Grant programs:

1. The provider incentive program should ensure that we are not creating a two-tiered system in which Medicaid is not fully integrated into the improved care delivery system enabled through this initiative;
2. The states must have an engaged partner with Medicare, and CMS must facilitate the coordination between state Medicaid agencies and Medicare related to HIT initiatives, EHR adoption, and meaningful use. This collaboration should address program requirements and infrastructure for both the Medicaid incentive payments and the Medicare incentive payments;
3. The provider incentive program should foster EHR adoption and meaningful use among eligible Medicaid providers pursuant to the NPRM, and strive towards including non-eligible providers that are critical to improve the quality and value of the Medicaid program, such as long-term care and behavioral health providers;
4. States should be explicitly permitted to use the 90/10 funding for infrastructure development, education and training to support *all* Medicaid providers, not just those deemed eligible under the NPRM. States should be allowed to provide these outreach and education activities through the provisions that allow states to "pursue initiatives to promote adoption" in accordance with sections 1903(a)(3)(F)(ii) and 1903(t)(9)(C) of the Social Security Act;
5. To encourage provider participation and successful use of incentives, CMS should appropriately tailor requirements to allow flexibility for both states and providers. CMS and the states must ensure adequate assistance and sufficient time for providers to "ramp up" around EHR adoption and meaningful use;
6. States must have support to adequately address limited staffing and lack of resources to implement, administer and monitor this program. States should be encouraged to share and combine processes, methods, and data across the

Medicare and Medicaid programs and across other state Medicaid provider incentive programs;

7. The proposed timeline to design and implement this program is aggressive, and should be balanced with the need to "get it right." Medicaid agencies and providers need even greater flexibility around (1) program requirements and (2) design and implementation timeframes; and
8. Due to the new and evolving nature of the provider incentive program, CMS should explicitly recognize the states ability to revise and redirect the program without penalty from CMS.

PROVISIONS OF THE PROPOSED RULE

Alignment of Medicare and Medicaid

Section II.A. Definitions Across the Medicare FFS, Medicare Advantage, and Medicaid Programs (Page 1847) §§ 495.2, 495.100, 495.200, 495.302

Section II.A.2.b. Common Definition of Meaningful Use Under Medicaid (Page 1851) § 495.6

- §§ 495.6; 495.8(2)(iv); 495.316(d)(2); 495.332(f)(2); Section II.A.3.d (Page 1873); Section II.A.3.e (Page 1890). The states support alignment across Medicare and Medicaid; however, the current clinical measures do not reflect key clinical services and issues for the Medicaid population, including behavioral health, dental, long-term care, and care coordination (particularly across physical and behavioral health care). The states recommend that CMS work with the Medicaid Medical Directors and ONC and consider the development and inclusion of clinical and non-clinical quality measures that are more representative of the Medicaid population. Examples of specific metrics are included below. Alternatively CMS and ONC should have a "placeholder" to accommodate data and interoperability for these measures.

  1. **Behavioral health care measures**: Behavioral health issues affect a large portion of the Medicaid population and should not be ignored. HEDIS measures exist for visits occurring after a psychiatric admission. Also, NQF has measures that focus on documentation of side effects of atypical antipsychotics, follow up visits for patients on stimulants, treatment of major depressive disorder and bipolar disease. More measures are in development by a NQF committee.
  2. **Dental care measures:** The states recommend a placeholder for nationally agreed upon dental clinical quality measures currently being developed by a newly formed Dental Quality Alliance convened by the American Dental Association. The states also recommend additional access measures. NCQA's HEDIS has an "Annual Dental Visit" measure that should be considered, as should a dental equivalent to the CHIPRA Core Measure pertaining to access to primary care providers. There are two CHIPRA Core Measures that can be revised to be more applicable across programs and plans (e.g., revisit specifications for eligibility, enrollment timeframes, gaps in coverage, etc. to create consistency across payers.)

3. **Long term care:** Multiple measures (drawn from the MDS) in this arena are already required by CMS. The states suggest making these readily available in real time to states to help with quality improvement projects.
4. **Care coordination (particularly across physical and behavioral health care):** NQF has started to develop a set of appropriate measures, and when they are fully developed, they could be a rich source of measures for this area. Furthermore, there is an existing measure in the National Quality Measures Clearinghouse, "Care coordination (CC): proportion of children needing more than one health care service who received coordinated care." The specifications for numerator and denominator are defined and are survey based and for children 3 months to 48 months of age only. This may also be a useful measure. Lastly, there are data elements that are required by JCAHO and recommended by NQF at the end of hospitalizations that could also be useful for care coordination activities.
5. **Special needs populations:** The care of special needs populations could be improved with the selection of condition-appropriate measures. Special needs populations include: children in foster care, developmentally disabled, blind, autism spectrum disorder, and others. The states recommend including a placeholder for measures that will be well-substantiated and nationally-recognized.

- The states recommend that new clinical quality measures be added as "placeholders" for care provided by non-eligible, but critical Medicaid providers. These critical providers are included below. The Medicaid Medical Directors would welcome the opportunity to further discuss the measure set with CMS:

1. **Community Mental Health Centers:** The states recommend having a placeholder for CMHC measures developed with the input of the CMHC organizations.
2. **Home Health:** Home health has extensive Medicare measures from the OASIS data set. The states recommend that CMS share this data with the states. Also, the states recommend having a placeholder here until specific measures can be developed/identified preferably by the home health organizations.
3. **Renal Dialysis Centers:** Dialysis centers have extensive measures under the Medicare program that relate to adequacy of dialysis and control of anemia. The states recommend that CMS consider including related measures as a part of this program.
4. **Other measures:** The states recommend that CMS maintain flexibility for the addition of other areas/providers that are yet to be identified or new centers of care that may develop in the future.

- 495.332(c)(1); 495.332(c)(11)(ii); 495.366(c); Section II.A.5.c (Page 1904). Section II.D.5 (Page 1941).The states request a joint approach with CMS to address the shared needs of the Medicaid and Medicare programs. A joint approach would enhance coordination between Medicaid and Medicare, reduce inefficiencies, help facilitate state and provider participation, and minimize burdens to payers and providers. It would also strengthen communication and coordination between

Medicaid and Medicare, and would be particularly relevant for hospitals that are eligible for both Medicaid and Medicare incentives. The states request that CMS work with the states to define a means for Medicare and Medicaid to share resources and information around educating and enrolling providers (as Medicare and Medicaid will reach out to many of the same providers/practice locations), making incentive payments, monitoring payments, attestation and other programmatic areas. The single provider election repository is an excellent starting point for coordination, and the states recommend that CMS work with the states to develop additional shared information resources.

- §§ 495.10, 495.10(d), 495.10(e); 495.332(c)(11)(ii); Section II.A.5.c (Page 1904); Section II.D.1 (Page 1928); The states request that CMS clarify the process that will assure Medicaid access to Medicare meaningful use data, at a minimum for (1) hospitals who receive both Medicaid and Medicare payments and (2) eligible providers that may switch once between the Medicaid and Medicare incentive programs. States request that CMS provide states with Medicare quality reporting/data in a timely fashion (for example, within 30 days of receipt of such information). Alternatively, the providers could be required to report separately to both Medicare and Medicaid.
- § 495.10; Section II.A.5.b (Page 1904). Because Medicaid and Medicare will be reaching out to the same provider community about the provider incentive programs, some states may be well-positioned to reach out to their community on behalf of both programs. Many states believe they know their provider community the best and are the most appropriate entity for outreach. At the least, states request that CMS regional offices partner with Medicaid agencies to discuss, develop and possibly implement collaborative provider outreach, engagement and education strategies. Having a "local" entity reach out to engage providers is likely to be more successful that an "unknown" entity, such as a national QIO, for example.
- §§ 495.314, 495.316(b)(1), 495.316(a), 495.316(c), 495.316(d)(2), 495.332(c); Section II.A.2.b (Page 1851); Section II.A.5.b (Page 1904); Section II.D.4.f (Page 1941). The states understand that CMS plans to develop a "deeming" process that would allow reciprocity between Medicaid and Medicare once a provider is determined eligible for one program or the other. This will reduce the administrative burden for both Medicaid and Medicare and the provider. The states are supportive of this approach to reduce administrative burden, to streamline the eligibility process, and to strengthen coordination between Medicaid and Medicare. However, we believe that this deeming process should not interfere with a state's ability, at their option, to impose additional meaningful use criteria beyond the CMS criteria for Medicare. We request that CMS affirm the ability of states to require additional meaningful use criteria for all eligible providers and hospitals (pursuant to §§ 495.316(a), 495.316(d)(2)), regardless of whether those entities were deemed eligible through Medicare.
- §§ 495.330; Section II.D.4.d (Page 1940); Section II.D.8 (Page 1945); Section II.D.9 (Page 1947). States request that CMS identify and develop "safe harbor" processes and methods for administering the incentive program that would assure states that if

these processes/methods are used, states would not be at risk if the processes/methods are less successful than anticipated. An example would include a process for auditing the adoption, implementation and update (AIU) process. If an audit approach is agreed to but is less than effective when applied, the state would not be responsible for re-auditing providers for previous years, nor would it be denied participation in the incentive program and lose the FFP.

- Section II.D.8. In recognition of the new and evolving nature of the two interrelated EHR incentive programs, the states seek support from CMS to bolster the success of both programs and allow states sufficient time and flexibility to make "mid-course corrections" as needed in their incentive program design and implementation. The states request that CMS dedicate staff and additional resources in each CMS region to work with states to refine and improve their SMHPs and the implementation of the EHR incentives program. For example, each CMS region could convene an annual meeting with its regional Medicaid programs to discuss progress and coordination of strategies across Medicaid and neighboring states.

State Match Requirements

Section II.D.2 General Medicaid Provisions (Page 1929) Part 495, Subpart D

Section II.D.9. Financial Oversight, Program Integrity and Provider Appeals (Page 1947) §§ 495.322, 495.366, 495.370

- Section II.D.2 (Page 1929); Section II.D.9 (Page 1947). The states request that CMS allow flexibility in how states calculate the 10% match rate. For example:

  (1) § 495.322. The states request that CMS allow in-kind contributions – such as state staff "on loan" to the Medicaid program for the provider incentive program – as part of the 10% state match. In today's economic reality of severe state deficits, states may otherwise not be able to secure the funding needed to participate in this program.

  (2) § 495.332(a)(8). The states request that CMS allow states to include anticipated savings generated from the health care system from EHR adoption and meaningful use as part of the state's 10% match during the implementation phase. If the ultimate goal is improved care and efficiency, and states are estimating a certain percentage of savings in their SMHP, it is logical that the states should include this assumed savings as part of their 10% match. For example, states could include anticipated savings to Medicare attributed to better management of the dual eligible population.

  (3) § 495.332. The states applaud the fact that CMS has allowed philanthropic funding to contribute to the state match throughout the years. The states request that CMS allow flexibility for entities contributing funding as part of the 10% match. Entities beyond non-profit philanthropies, such as all-payer regional alliances should also be allowed to contribute funding.

Eligible Medicaid Providers

Section II.D.3. Identification of Qualifying Medicaid EPs and Eligible Hospitals (Page 1929, 1932) §§ 495.10(e), 495.304, 495.306

Section II.A.6. Hospital-based Eligible Professionals (Page 1904) §§ 495.4 (hospital based EP), 495.304(c)

- § 495.302 (patient volume); Section II.D.3.c-d (Pages 1931-1932) There is conflicting language between the preamble and the draft CFR language in how an eligible Medicaid provider is defined – specifically whether Medicaid encounters or Medicaid patients are used in calculating eligibility. Please define "encounter".
- § 495.304(c); Section II.D.3 (Page 1929). The states request that CMS revise the methodology to allow flexibility in how eligible Medicaid providers are identified. The states recognize that the 30% threshold is mandated by statute; however, without access to all-payer data, states are unable to identify providers with 30% Medicaid encounters. Furthermore, a recent study by the George Washington University found that a practice with 30% Medicaid patient load may not be a financially viable entity; in other words, states may not find many practices with such a large Medicaid volume.[1] In order to reach a larger group of practices, CMS should consider modifying the requirement to include a range of Medicaid penetration. For example, 10% or 20% to 30% Medicaid encounters could be the eligibility threshold.
- § 495.302 (Patient volume), 495.306(b); Section II.D.3.d (Page 1931). As another alternative, the states request that CMS include multiple methodologies – one of which would be the 10% or 20% to 30% range - from which states could choose. States would choose their methodology based on their access to data and infrastructure and could commit to a methodology for a period of time. Potential methodologies could include the following:

  (1) CMS and the states determine what the all-payer "denominator" would be;

  (2) CMS and the states identify a per provider raw number threshold of Medicaid encounters (with variances related to the size of the practice);

  (3) CMS and the states could identify a raw number threshold of Medicaid patients per provider;

  (4) A state could array its providers based on Medicaid patient load and target the highest-volume providers (e.g., the top 20% of providers);

  (5) §§ 495.302(patient volume), 495.304(c). For group practices who don't uniquely assign patients, CMS could work with the states to develop a formula for aggregate Medicaid volume for the practice;

  (6) States could propose another methodology for CMS consideration.

  This "menu" approach would allow states flexibility to identify eligible providers and likely increase the "universe" of providers potentially eligible for the program, which would help achieve CMS' goal of widespread adoption.

[1] Boosting Health Information Technology in Medicaid: The Potential Effect of the American Recovery and Reinvestment Act. Brad Finnegan, M.P.P., Ph.D. [cand.], Leighton Ku, Ph.D., M.P.H., Peter Shin, Ph.D., M.P.H., Sara Rosenbaum, J.D., July 7, 2009.

- Please note that the majority of Medicaid providers do not use an EHR or submit electronic claims and therefore it will be extremely tedious to capture a numerator and denominator until the time when the providers have adopted an EHR.
- § 495.316(d); Section II.A.2.c (2) (Page 1859). The states request that CMS reconsider the proposed meaningful use requirement of greater than 50% of patient encounters during the EHR reporting period occurring at a practice(s)/location(s) equipped with certified EHR technology. Some providers who operate in multiple practices will need to install more than one EHR system in order to meet this threshold. Given the limitations on reimbursement funding, this could create significant financial disincentives for adoption. To increase the "universe" of providers striving to achieve MU, CMS should provide flexibility to eligible providers to implement EHRs in the location where they provide the majority of their encounters.
- §§ 495.304, 495.318, 495.320, 495.332(a)(ii); Section II.D.3.b (Page 1930). The states request that CMS recognize that the Act excludes many relevant and key providers from participating in the incentive program. Specifically, the states argue that community mental health centers and other behavioral health providers, nursing homes, community long-term care providers, and home health care providers should be eligible for incentive payments as they are critical partners in improving the quality and coordination of care for the Medicaid population. The states recognize that this is a statutory issue, but feel strongly that exclusion of these critical providers impacts Medicaid's ability to improve the quality and efficiency of care. The states recommend that CMS allow states and the regional extension centers (RECs) to provide education and training, technical assistance, and infrastructure as relevant to support these excluded providers pursuant to the 90/10 funding. By including these excluded providers in education and training, the states can set the stage for eventually achieving the long-term goal of helping all providers serving Medicaid exchanging data and be meaningful users of EHRs. §§ 495.304, 495.318, 495.320
- §§ 495.302 (practices predominantly, needy individuals); 495.306(c), 495.366(b)(4). Throughout the NPRM, additional requirements for Medicaid EPs practicing predominantly in a Federally Qualified Health Center (FQHC) or Rural Health Center (RHC) require that these providers must have a minimum of 30 percent patient volume attributable to ''needy individuals." Section 495.302 defines "practices predominantly" for an EP as an EP for whom "the clinical location for over 50 percent of his or her total patient encounters over a period of 6 months in the most recent calendar year occurs at a federally qualified health center or rural health clinic." The 30 percent requirement added by the HITECH Act to Section 1903(t)(2)(A) of the Social Security Act does not state whether that percentage applies to each provider at the FQHC or the FQHC itself. We believe that this provision is intended to apply to the FQHC as an entity rather than to each health center provider. We therefore recommend that CMS state clearly in the final version of the regulations that the 30 percent criterion used to determine the patient volume of needy individuals applies to the FQHC as an entity and not to each of its individual providers. This modification to the regulations will assure fulfillment of the clear

intent in the HITECH Act to ensure that FQHCs and RHCs can secure incentive payments directly for EPs who practice predominately in those locations.

- Section II.D.3.b (Page 1930). Many physicians, as well as non-physician providers, are part-time providers. In order to be as inclusive as possible, the states recommend that eligible providers can be part-time providers. The NPRM is silent on this point.
- §§ 495.102(d), 495.366(5); Section V.G.6. (Page 1983). Please confirm that Medicaid EPs will not be subject to Medicare penalties. For example, if a provider begins in the Medicare incentive program, but switches to the Medicaid incentive program, will that provider be financially penalized by Medicare if it does not achieve meaningful use? If so, this would be contrary to the statutory distinctions from the Medicaid incentive program, in particular the longer time frame for the incentives and achieving meaningful use. Furthermore, it could be an overwhelming reason for many providers not to participate in the program.
- § 495.310(e); Section II.D.4.g (Page 1941). For providers serving residents in bordering states, it will be challenging for the Medicaid agency to identify whether the provider is eligible, as the state will not have access to claims data for residents in neighboring states. The states request that CMS provide financial and technical support for interstate cooperative agreements to verify eligibility or include this information in the single provider election repository. Alternatively, CMS and the states could develop a method for qualifying a provider based on data from only one state. Or, CMS could give explicit authorization for states to exclude Medicaid patients in the bordering state from the 30% calculation.
- §§ 495.10(e), 495.366(b)(5); Section II.A.5.b (Page 1904).Please identify how eligible Medicaid providers will be approved for Medicare incentives if they change to the Medicare incentive program. The states suggest that CMS extend its deeming process to EPs who satisfactorily participate in a Medicaid program as eligible for Medicare with subsequent compliance of additional Medicare reporting, and vice versa.
- § 495.304(e)(i); Section II.A.6 (Page 1904). The states are concerned that some hospital-based providers will not have access to the hospital's EHR and will be completely without access to this critical tool. Therefore, the states recommend that CMS expand eligibility for hospital-based providers if (1) 5% to 10% or more of the provider's outpatient services are rendered outside the hospital, establishing that if 5%-10% of services are non-hospital-based the provider is not furnishing substantially all of his or her services in a hospital setting, or (2) the hospital does not provide a qualified EHR. Alternatively, the states recommend that CMS delete "outpatient" from the definition of hospital-based.
- § 495.4; Section II.D.3.b (Page 1930). The states request that CMS include in its definition of eligible provider "a provider who treats patients outside of the hospital setting, even if the majority of their time is spent in an 'outpatient setting.'"
- Section II.A.6 (Page 1904); Section II.D.4(4) (Page 1935). Please clarify how incentive payments to hospitals will be affected if a hospital undergoes a change in

ownership. Specifically, does the time period and incentive program start over again under new ownership?

Meaningful Use

Considerations in Defining Meaningful Use—Stage 1, 2, and 3 (Page 1852) § 495.4

Section II.A.1.f. Definition of Meaningful EHR User (Page 1850)

Section II.A.2 Definition of Meaningful Use (Page 1850)

Section II.A.3 Reporting on Clinical Quality Measures using EHR by EPs and All Eligible Hospitals (Page 1870) §§ 495.6(d)(3), 495.6(e)(2), 495.8, 495.314(b)(2), 495.332(a)(8), 495.332(c)(4)

Section II.A.4. Demonstration of Meaningful Use (Page 1903)

- §§ 495.8, 495.314(a)(ii); Section II.A.2.a-d (Pages 1850-1870). The states strongly support CMS' effort to align the Medicaid and Medicare programs, including around meaningful use. The states believe this is important to reduce provider confusion, and to create efficiencies for Medicaid and Medicare. That said, the states request that CMS allow states and practices increased flexibility in demonstrating meaningful use. Tremendous variability in health IT hardware, software and the requisite knowledge base exists within each of our various states. Some entities are very sophisticated in their use today while others do not even own any hardware. As the states see it, the major beneficial movement and the focus of our efforts should be on moving the vast majority of eligible hospitals and eligible providers with no or inadequate EHR systems to participate with certified EHR technology at a minimal level (which can be later advanced) as opposed to not participating because the requirements are too stringent. The major benefit of the incentive program is to facilitate widespread adoption of HIT; this is not achieved by improving the capacities of providers that have already begun using the technology at a sophisticated level. This goal will not be reached by setting the bar so high that many providers decide to avoid participating or to delay participation. Hence, the states recommend a combination of:

  (1) Lowering the compliance bar (using the alternative measure methodology proposed in the next bulleted section);

  (2) Providing a small core set of high value, evidence based, peer-reviewed HIT and clinical quality measures that are used universally, thereby helping to build statistical validity for the findings from those measures;

  (3) Providing an additional "menu" of evidence-based HIT and clinical quality measures, giving priority to evidence-based measures for providers to pick from to earn additional incentives;

  (4) Delaying some measures/requirements to a later stage;

  (5) Requiring the HIE to be capable of extracting all required health IT and quality reporting measures; and

(6) Over time (or perhaps by stage 2) only using HIT functionality and clinical quality measures that are supported by peer reviewed, evidence-based literature which demonstrates that those measures promote health and/or safety.

- Section II.D.7 (2) (Page 1941). Given that AIU involves significant practice workflow redesign and that the states overarching goal is to increase the level of provider participation, the states recommend the following modifications:

  (1) **Only** require AIU for Year 1 *and* Year 2.

  (2) Allow AIU compliance *to be further defined* (*beyond what is already in the proposed rule)* as:

    - The provider developing, submitting, and following a customized plan for the necessary workflow changes with timelines (whose development can be assisted by the Regional Extension Centers);
    - The provider would have to meet their timelines for each year in Stage 1 to qualify for the incentive payment; and
    - The AIU plan timelines would have to be structured so submission of HIT and clinical quality measures would begin in Stage 2.

  (3) All of the Stage 2 measures, both HIT and clinical quality, should be supported by evidence based, peer reviewed literature. Further, CMS and the states could assess progress to date and the challenges that Medicaid providers face in receiving or not receiving incentive payments. This "real world" information could help inform decisions around Stage 2 measures and would support more Medicaid providers in succeeding in the program.

  (4) The Stage 2 quality measures would consist of only a small core set of measures (3-5) within a specialty/in each category which would be required for a basic incentive payment.

  (5) Additionally, a menu of measures beyond the core could be used to provide additional incentive payments.

  (6) Providers that can meet Stage 2 levels of performance in Year 1 should be rewarded by the incentive program as are other Year 1 qualifiers.

- § 495.6; Section II.A.3.c-e (Pages 1872-1895). The states recognize and support the theoretical concept of having a core set of measures; however, the states recognize the difficulty of developing a core set of measures that is sufficiently ubiquitous and relevant to *all* providers, as opposed to a specialty group, which is more achievable. The states recommend that CMS eliminate the proposed core measures for *all* providers.

- The states are interested in discussing with CMS whether/how meaningful use of certified EHR technology could be demonstrated by using the EHR to coordinate care in the form of a patient-centered health home, disease registry or some other way that demonstrates a collaborative approach to managing patients using technology. These uses are much more patient-centered and do not focus on the provider, as the current

measures do. Did CMS consider a more patient-centered, holistic in its decision-making?

- § 495.6; Section II.A.2.d-e(2) (Pages 1858-1870) Three HIT functionality measures are particularly burdensome and costly for eligible providers:

  (1) reminders for follow-up care (patients older than 50 years)-§ 495.6(d)(4);

  (2) providing patients with an electronic medical summary-§ 495.6(d)(5); and

  (3) timely electronic access within 96 hours to their electronic health record (remote access to information)-§ 495.6(d)(6).

  The goal of patient engagement is an important one; however, these requirements would likely be burdensome for providers to implement given the likely user support and follow up needed for the patient population, particularly for primary care practices, and could therefore act as a significant deterrent to participation in the incentive program. The states recommend that CMS and ONC consider other entities that could be better suited to provide the information for these measures to patients and their families. The HIE, for example, could serve as the aggregator across providers and "push or pull" the information as needed. They could also provide technical support to the patient or patient designee in a more efficient manner (i.e., not requiring each provider to assist the patients in this manner.) There will likely be significant literacy challenges and technical challenges that are unanticipated and practices will not have the staff or skill set needed to address these challenges.

- § 495.6(e)(i); Section II.A.2.d. (Pages 1854-1870). The NPRM states that for the HIT functionality measures, for EPs, CPOE is used for at least 80 percent of all orders. This same measure for hospitals requires only 10 percent of all orders. The states recommend parity between the requirement for EPs and hospitals, particularly given that hospitals have greater experience and penetration with HIT than other providers. The percentage should be closer to the requirement for hospitals.

- The states recommend that, like hospitals, EPs should be able to receive partial payments for HIT functionality and quality measures. This flexibility will create incentives for practice that might otherwise be overwhelmed by achieving the full measure set, and, in turn, increase the likely participation of eligible providers.

- § 495.6(b)(5); Section II.A.2.d (Page 1854). One of CMS' goals for this program is to reduce health care disparities and inequities. As such, the states recommend that HIEs could incorporate the use of race, ethnicity and language data – in a later stage – and stratify performance and identify disparities in care.

- § 495.6. There are currently no NQF-endorsed or other nationally accepted quality measures for dentistry. However, the states recognize that the American Dental Association (ADA) has recently been designated by CMS as the convening organization for the development of quality measures for dentistry through the Dental Quality Alliance (DQA). Quality measures developed by the ADA and its partner organizations on the DQA should be recognized in the future as the dental quality criteria for use in meaningful use regulations. Dentists, however, will most likely need a later start date for the implementation of reporting quality measures than might

other health care providers. Additionally, while dentists generally collect patient-reported information on immunizations, they do not administer immunizations at this time. As only the reporting of patient-provided information will be available from dentists for submission to immunization registries at this time, we recommend that dentists not be required to report to those registries. Dentists should, however, be able to receive and view immunization information. Also, while many dentists are not currently able to maintain an up-to-date problem list of current and active diagnoses based on ICD-9-CM or SNOMED CT®, the ADA is developing clinical terminology subsets and value sets for use to support EHRs, including the required reporting of diagnostic data. The Final Rule should include reference to subsets and value sets of these terminologies.

- § 495.6. Because smoking is not the only form of tobacco use with harmful health effects, the states recommend substituting "tobacco use," rather than "smoking," for this objective. Dentists are often the first health care providers to see the effects of smokeless tobacco use, which may start as early as kindergarten or first grade (e.g., 21% reported among Northern Plains Indian kindergartners[2] and 36% among rural 1st graders[3]). Therefore, we recommend changing the meaningful use Stage 1 objective, currently stated as "Record smoking status for patients 13 years old or older," to "Record tobacco use status for patients 5 years old or older." Likewise, we recommend changing the certification criterion to support achievement of Stage 1 meaningful use from "Enable a user to electronically record, modify, and retrieve the smoking status of a patient to: current smoker, former smoker, or never smoked" to "Enable a user to electronically record, modify, and retrieve the tobacco use status of a patient to: current tobacco user, former tobacco user, or never used tobacco."

- § 495.6. Similarly, we recommend that Tables 6, 10 and 11 on pages 1891-1893 be modified regarding advising smokers to quit. Therefore, we suggest changing the measure, currently titled as "Preventive Care and Screening: Advising Smokers to Quit," to "Preventive Care and Screening: Advising Tobacco Users to Quit."

Adoption Entities

Section II.D.3.e. Entities Promoting the Adoption of Certified EHR Technology (Page 1932) § 495.302

- §§ 495.302(k), 495.310. The states request further definition of "promoting" certified EHR adoption.

- § 495.332(c)(9)(ii); Section II.D.3.e (Page 1932). States request that CMS confirm that states will determine what entities are eligible as adoption entities and that states

[2] Centers for Disease Control (1988). Prevalence of Oral Lesions and Smokeless Tobacco Use in Northern Plains Indians. MMWR Weekly. http://www.cdc.gov/mmwr/preview/mmwrhtml/00001287.htm, accessed 3/4/10

[3] Lisnerski DD, McClary CL, Brown TL, Martin JP, Jones DR. (1991) Demographic and predictive correlates of smokeless tobacco use in elementary school children. American Journal of Health Promotion. http://www.ncbi.nlm.nih.gov/pubmed/10146841?itool=EntrezSystem2.PEntrez, accessed 3/1/10

can prohibit any direct communication by these entities to providers until the state has determined whether an entity is eligible and established guidelines for ensuring voluntary provider participation are developed.

- § 495.310; Section II.D.3.e (Page 1932). The states request that CMS provide national standards around the responsibilities and oversight of the adoption entities. For example, CMS could develop standards around: ensuring compliance with kickback prohibitions; ways to monitor eligible provider enrollment by the entity; technical assistance adoption entities must provide to providers; what monitoring must occur of adoption entities; and alignment of adoption entities in promotion activities.
- § 495.310(k)(1)(ii); Section II.D.3.e (Page 1932). If a provider has voluntarily given his/her incentive payment to an adoption entity that is an IPA or plan, for example, and the provider leaves the IPA or plan, does the provider recoup the incentive payment or does the adoption entity retain it? CMS should establish standard rules for states to conform to in this regard.
- Section II.D.3.e (Page 1932). Is it a mandatory requirement that a state have an adoption entity? The states are concerned about the likely "gaming" that could occur and the resulting burden on administration, oversight and monitoring of the adoption entity program.

Rural Areas and States

Section V.C. Regulatory Impact Analysis--Small Rural Hospitals (Page 1974)

- Section V.C (Page 1974). States have concerns that many providers serving rural and frontier areas will not have sufficient broadband coverage to take advantage of the provider incentive program, and that the disparity between rural and non-rural areas will continue to widen as a result. It would be helpful to have in one location a chart clarifying the various funding streams available for broadband and HIT adoption.
- Section II.A.2.c (2) (Page 1859). The states request that CMS revise the 50% patient population in a given site requirement so that rural providers could reach a lower threshold – either within a single practice or across multiple locations - with the understanding that they will work toward the full deployment of EHRs across sites over time.

Tracking, Monitoring, and Reporting of Provider Incentive Program

Section II.D.8. Overview of Conditions for State to Receive Federal Financial Participation for Incentive Payments and Implementing Funding (Page 1945) §§ 495.318, 495.320, 495.322, 495.324, 495.326

- Section II.D.4.d (Page 1940); Section II.D.9 (Page 1947); §§ 495.310, 495.366. States request that CMS confirm that state Medicaid agencies do not have to recover incentive payments made to Medicaid providers who do not ultimately meet meaningful use requirements within the time period for the Medicaid program. The

threat of recovery of incentives would be a significant deterrent to provider participation as well as an increased burden on states administering the program.

Dual Eligibles

Section II.A.3.k Addressing Dually-Eligible Medicare/Medicaid Beneficiaries under HITECH (Page 1902) §495.310(j)

- Section II.A.3.k (Page 1902). As noted in previous comments, the states want to reiterate the need to coordinate and streamline program development efforts as much as possible with Medicare. The states request that the two programs develop combined and shared methods and processes and exchange of data. The states recommend that CMS develop a national or regional patient directory that is a Master Patient Index (MPI) for dual eligibles. The MPI would uniquely identify dual eligible patients to facilitate the exchange of clinical data between Medicare and Medicaid providers. Although practices will have access to clinical data via the EHR, ensuring that health information for duals is successfully exchanged will be particularly challenging. As such, developing a MPI would be helpful. The rationale for this directory is to ensure that information for these very vulnerable patients will be readily exchanged to achieve the goals of the Act.

Adoption, Implementation and Upgrading (AIU)

Section II.D.4.c. Alternative and Optional Early States Implementation to Make Incentive Payments for AIU (Page 1939) §§ 495.302 (Adopt, Implement, or Upgrade)

- Section II.D.4.c (Page 1939). States are concerned that the early adoption with the AIU program is not feasible given the timeline, even if states wanted to implement it. Despite CMS' best intentions, states now face strong political pressure to participate in this "voluntary" program, with limited time to implement the incentive program after the release of the final rules. If CMS believes that early availability of the AIU incentives is critical, it should work with states to develop a streamlined approval process for a targeted I-APD to enable early implementation of this portion of the program that can be submitted in advance of a completed and approved SMHP. If an expedited approval of the I-APD is not an option then the final rule should change the availability of the AIU incentives back to 2011.
- Section II.D.4.c (Page 1839) Given CMS' rationale for early availability of AIU, the states believe the goal of this incentive is to help defray some of the costs of AIU to foster certified EHR adoption. As such we believe "proof" of AIU should not require completion of AIU but demonstrated commitment to AIU. For example, a proof of purchase, a schedule for training and implementation, and periodic reporting from practices on progress on the schedule could suffice. States should have flexibility to define what is sufficient to trigger payment.
- Section II.D.7 (2) (Page 1941). States recommend that CMS clarify if "upgrade" does or does not apply to an already certified EHR. In other words, we recommend that

CMS confirm that an upgrade is intended to enable a provider to expand existing functionality of an EHR so that it meets the certification criteria.

Feasibility of State Implementation and Administration of the Program

Section II.D.8. Overview of Conditions for States to Receive Federal Financial Participation (FFP) for Incentive Payments and Implementation Funding, (Page 1945).

- Section II.D.8. (Page 1945). States request that CMS clarify the level of detail that will be necessary for states to provide in their strategic HIT plan and SMHP. Workgroup members expressed the concern that they are "trying to land a plane while the runway is being built." CMS appears to assume that planning and implementation will occur simultaneously.
- Section II.D.8. (Page 1945). The states request clear language that they are afforded revisions to and redirection of their SMHP, P-APDs and I-APDs without penalty from CMS, as long as there is a good faith effort by the state to strongly pursue a successful program. This request is grounded in the new and evolutionary nature of the provider incentive program.
- § 495.332 a(8); Section II.D.8. (Page 1945). The states are concerned about the language in CFR 495.332 a (8) which requires them to "ensure" improvements in health outcomes, clinical quality or efficiency with the provider incentive program. If this is a goal of the incentive program shared by both Medicaid and Medicare, this should be the joint responsibility of both states and CMS, with CMS providing the leadership on how to accomplish this goal. If this is not the intent, CMS should revise the requirement as such.
- Section II.D.8. (Page 1945). The states recommend that CMS revise the requirement that states must validate data used to calculate clinical measures. States will not have the ability to validate all-payer data used to calculate measures when they only have the right to review data for Medicaid patients.
- §§ 495.332(a)(11); Section II.D.8. (Page 1945). Consider developing a multi-state task force that will look at shared solutions and approaches to addressing the needs of underserved and vulnerable populations (495.332 a(11)) particularly since many of their needs are addressed by providers excluded under the incentive program.
- §§ 495.332, 495.336, 495.368; Section II.D.8. (Page 1945). The states are concerned that gaps exist between the practices targeted by the REC and Medicaid eligible providers. The states have concerns that Medicaid providers will not receive the support needed. For example, given the variance in approval, implementation, operations and available resources of the 60 RECs across the country, the states are concerned about whether the RECs will be in place and operating in time to support the Medicaid providers in reaching meaningful use. States are also concerned that the level of resources to the RECs will not be sufficient to cover the needs of the eligible providers. If there are gaps in timing of REC approval and operations and resources, the states seek assurance that states can augment the support that needs to be provided to the Medicaid practices.

Single Provider Election Repository/National Level Repository

Section II.A.5.c Data to be Collected (Page 1904); § 495.332

Section II.D.5.c. Single Provider Election Repository (Page 1904); § 495.332(c)(1).

Section II.D.4.e Avoiding Duplicate Payment (Page 1940) §§ 495.208, 495.212(a), 495.332(d)(i)

- Section II.D.5.c (Page 1904). The states applaud the creation of a single provider election repository and recommend that it include sufficient functionality to limit the burden placed on both providers and states to determine eligibility and coordinate verification and oversight processes. The repository should have frequent updates and notifications regarding changes in information and provider status. Until the system is fully tested and operable, the states request that CMS provide resources to the states to ensure that the states have the information needed for coordination.
- § 495.332(c)(1); Section II.D.5.c (Page 1904). Please confirm that the repository will make available enrollment information for providers in neighboring states.

Industry Costs and Adoption Rates

- Section V.G.4.a. Costs of EHR Adoption for EPs (Page 1976). Adoption of HIT will have significant economic impact on the vast majority of dental offices. The cost impact related specifically to dentistry may be higher than that of medicine in general due to the current lack of commercially available dental EHR software that is either a "Complete EHR" or an "EHR Module" certified through the existing Certification Commission for Health Information Technology (CCHIT) standards. Certification of a dental component to an EHR has not been and is not now a priority for the CCHIT. The lack of proven interoperability between medical and dental EHRs will be a significant barrier to not only the adoption and use of EHRs by dentists but also to meeting the criteria for meaningful use for dentistry. Whether the dental components of the EHR are run as an EHR Dental Module or as one component in an integrated Complete EHR, we believe that the required unique dental content should be fully included in the overall EHR implementation.

GENERAL QUESTIONS REGARDING THE REGULATION

In addition to these specific comments, states had a number of general questions relating to the regulation as well as the administration of the incentive program. We request that CMS clarify the way that states are expected to implement and administer the program. Specifically, states would like to know:

1. How can states access the national HIE to assist with program administration? For example, some states have expressed an interest in using the HIE for medical reviews or for disability determinations. Will there be a way for Medicaid, and

other payers, to connect to the ONC funded HIE to retrieve medical information?

2. It initially appeared that the maximum amount EPs could be reimbursed was the amount listed by year for a total of no more than $63,750 (year 1 amount - $21,250 and subsequent years - $8,500). Upon further review, it appears that states reimburse EPs at 85% of their incurred system installation and maintenance costs, but not to exceed the amounts listed above. Can CMS offer further clarification on how states are to determine/calculate the amount the EPs should be reimbursed? Will states need to collect and/or provide copies of EPs' receipts or bills for EHR related costs?

3. It appears that EPs are supposed to submit clinical quality measures electronically to the states when due. Several states have aging Medicaid Management Information Systems that may not be capable of accepting this data/information. Will CMS expect the states to utilize and report this data immediately?

4. §438.6(c)(5)(iii). The NPRM states: "We expect States to consider utilizing all existing fiscal relationships as intermediaries for disbursing the incentives. Since many States never pay the provider directly, but rather pay a managed care plan, which then pays the provider, the State may have no existing relationship and decide to contract with the managed care plan to pass this incentive to the EP. States must establish a process to ensure that any existing fiscal relationships with providers to disburse the Medicaid incentive payments through Medicaid managed care plans does not result in payments that exceed 105 percent of the capitation rate, in order to comply with the Medicaid managed care incentive payment rules at §438.6(c)(5)(iii) and a methodology for verifying such information." Can CMS clarify what this actually means in terms of exceeding 105% of the capitation rate?

5. Similarly, if a provider operates under multiple reimbursement systems (i.e., some providers are paid through Medicaid fee-for-service and some are under Managed Care Organizations), will the provider be held to the 105% of capitation rate limit?

6. The NPRM indicates that providers can switch between the two programs once but the switch cannot occur after 2014, and that a provider can only receive the maximum amount allowed under the incentive program that they end up in. If an EP decides to enter the Medicare program the first year and then switches to the Medicaid program the second year, would they be able to get additional funding for their first year of payment since it was less under Medicare or would their future payments be tied to the maximum amount allowed for subsequent years, resulting in slightly less than the $63,750 that is available under Medicaid?

7. Is there a timeframe for Adopting, Implementing and Upgrading that is similar to the 90-day period for demonstrating meaningful use in the first year? For example, would adopting on December 31 meet the requirements, or would the

individuals need to adopt 90 days prior to the end of the year?

8. States request more clarity regarding how to determine eligible providers. For example, podiatrists and chiropractors are covered by Medicare's "physician" definition, but are not explicitly listed as a Medicaid eligible provider. Will the Medicaid eligible physicians be based upon the state's definition of Medicaid physicians?

9. How will a FQHC Look-Alike be treated for eligibility and reimbursement in the incentive payment program?

10. Is a provider required to be actively enrolled in the Medicaid program to be considered for an incentive payment?

11. Are the EHR incentive payments required to be declared as income? If so, are Medicaid agencies and providers expected to report the Medicaid incentive payments to the IRS?

12. What is the required sequencing between Implementation Advanced Planning Documents and State Medicaid HIT Plans? Do SMHPs need to be submitted and/or approved prior to an IAPD?

13. Will states need to go through a formal rulemaking process in order to define providers, meaningful use, and other considerations for the EHR Incentives Program? Formal rulemaking will be a lengthy process in many states, and will delay the start-up of the overall incentives program.

14. Do states need to file a State Plan Amendment to incorporate the SMHP into their State Plan, or will a SMHP be able to stand alone? If the SMHP can stand alone, will the state need to file a SPA that references the SMHP in their state plan?

15. In the Narrative, on page 1937, CMS Notes: "*Finally, these tables do not represent EPs whose incentive payments may be reduced because net average allowable costs may actually be lower than $25,000 in the first year, or $10,000 in subsequent years, due to payments from other, non- State/local sources*." What is meant by non-State/local sources and how are Medicaid agencies expected to determine if EPs have received any payments from these sources?

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In summary, NASMD would like to emphasize the need for flexibility regarding timelines and provider requirements. We believe that HIT technology must be developed in a manner that enables providers to use the technology in a meaningful way that improves patient outcomes and lowers costs. However, a substantial number of providers currently have low technological capabilities, and we believe that the current meaningful use criteria and timelines will create disincentives to participate for providers without significant experience using technology in their practices. By lowering the initial meaningful use criteria, and establishing more gradual benchmarks that lead to a fully integrated HIT and HIE environment, CMS can engage a broader range of providers to initiate EHR/HIT adoption.

Furthermore, more communication and collaborative planning between states and both the Medicare and Medicaid offices at CMS will strengthen the entire initiative and its overall success. We appreciate the strong partnership that CMS has developed with NASMD and the states through the Multi-State Collaborative, and thank CMS and ONC for their active engagement and support of state Medicaid agencies' initiatives through this project. CMS and the states have truly established collaborative relationships that support and strengthen state Medicaid agencies' EHR/HIT projects. However, we would like to emphasize the need for more involvement with the entities responsible for Medicare EHR adoption in order to ensure that the projects are truly integrated and coordinated. It would not be prudent or responsible to develop two parallel but unintegrated HIT initiatives through Medicare and Medicaid. We believe that individuals responsible for the Medicare incentive payment program should be included in this collaboration as soon as possible.

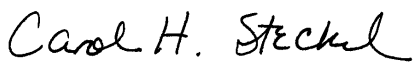
NASMD is excited by the potential of the Medicaid EHR incentive program and by the ability to expand upon the lessons learned through the Medicaid Transformation Grants and other state HIT initiatives. We would like to thank CMS and ONC for the work that you have put into developing these regulations, and CMS for the work that you have done with states to design, implement, and evaluate the Transformation Grants. The lessons learned from those projects will be crucial as we move forward with the EHR and HIE initiative. We look forward to continuing to work with you to ensure that Medicaid, Medicare, and the private sector collaborate effectively to foster meaningful, widespread adoption and utilization of health information technology.

Should you have any questions please contact me at 202-682-0100 x299.

Sincerely,

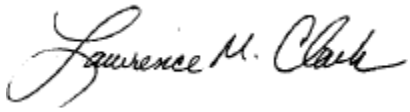
Ann Clemency Kohler
NASMD Director

Sincerely,



Carol Steckel
NASMD Chair
Multi-State Collaborative - Co-Chair

Sincerely,



Lawrence Clark
Multi-State Collaborative - Chair

Cc: Cindy Mann